

ACTIONS TAKEN BY FDA CENTER FOR VETERINARY MEDICINE

The following corrections or additions to the January 15, 1997 list were made in January 1997.

New Approvals

ANADA Number: 200-137

ANADA No.: 200-137
Pioneer Product: 046-724
Trade Name : Gentamicin sulfate solution
Ingredients: Gentamicin sulfate
Sponsor: Phoenix Pharmaceutical, Inc.
Approval Date: 11/13/96
Status : Prescription Only
Route : Intrauterine
Species: Equine
Drug Form: Liquid (solution)
Concentration: 100 mg/mL
Indications: For the control of bacterial infections in the uterus (metritis) in horses and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

21CFR 529.1044a

Suitability Petition Action

No.: 96P-0438 CP1
Sponsor: Pharmacia & Upjohn
Petition: Request permission to file an ANADA for a generic new animal drug which differs from that of the pioneer product only in the formulation and method of oral administration . The product would be formulated as a powder and administered orally once per day in a small amount of palatable feed. The pioneer product is Tribriksen 400 Oral Paste, NADA 131-918, sponsored by Mallinckrodt Veterinary, Inc.
Action: Approved on 01/10/97.

Amendment to the Regulation

The regulations are amended to more clearly reflect the currently approved conditions of use of tripelethamine hydrochloride, NADA 6-417, sponsored by Solvay Animal Health, Inc. The NADA provides for use of tripelethamine hydrochloride injection for antihistaminic therapy in horses and cattle. The amendment provides for the tolerance for drug residues in edible cattle tissues and in milk and the corresponding drug withdrawal and milk discard periods. When the NADA was reviewed under the National Academy of Sciences/National Research Council Drug Study Implementation Program and the results of the review finalized in 1983, this information was inadvertently omitted from the regulations. The tolerance for tripelethamine residues in uncooked edible tissues of cattle is 200 ppb, and in milk is 20 ppb. The withdrawal period for cattle is 4 days and the milk discard period is 24 hours (two milkings). A withdrawal period has not been established in preruminating calves. The product should not be used in calves to be processed for veal.

21CFR 556.741 and 522.2615